

1645



IN THE UNITED STATES PATENT OFFICE

Applicant: Ashley J. BIRKETT )  
 ) Attorney Docket:  
U.S. Serial No.: 10/082,014 ) 4564/85124  
 ) ICC-130.0  
Filed: February 21, 2002 )  
 ) Art Group:  
Title: IMMUNOGENIC HBc CHIMER ) 1645  
 )  
PARTICLES STABILIZED WITH )  
 )  
AN N-TERMINAL CYSTEINE ) Confirmation No:  
 ) 4213  
Examiner: Not yet assigned )

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.97, a list of documents that may be material to the examination of this application is provided on the attached Form PTO/SB08. Listed Documents A1 to A148 are U.S. patents, foreign patents and pertinent articles that may be relevant to the examination of the present application. Copies of Documents A1 to A148 are bound and enclosed herewith.

No inferences should be drawn that the attached list represents a comprehensive investigation, or that any material disclosed is equivalent to the subject invention. In addition,

U.S. Serial No. 10/082,014  
INFORMATION DISCLOSURE STATEMENT

none of the documents that have publication dates prior to the priority date of the above application anticipate the invention in this application.

The cited documents disclose numerous specific features. There has been no attempt to list each and every feature disclosed by each document. The Examiner is requested to review the documents and determine the extent of the materiality of the document disclosures with respect to the present invention.

The discussion of any art and the citation of any document herein is not to be construed as an admission that the art or document disclosure is necessarily within the invention field of endeavor, that the art or document disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that the art or document disclosure is otherwise necessarily prior art as defined by the patent law with respect to the instant invention and application.

Also, there is reserved the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosures of the art and documents recited herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

**U.S. Serial No. 10/082,014**  
**INFORMATION DISCLOSURE STATEMENT**

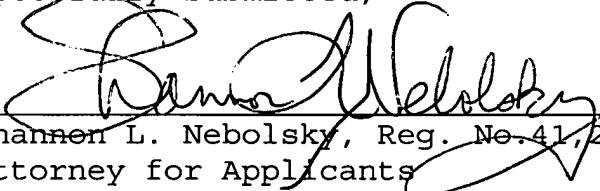
The recitation herein of the art and documents is not to be construed as an assertion that more pertinent art could not possibly be in existence.

No fee or petition is believed to be necessary for the consideration of this Information Disclosure Statement. However, should any fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

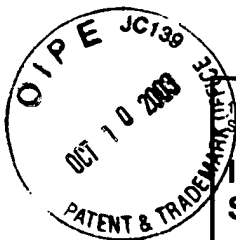
By

  
Shannon L. Nebolsky, Reg. No. 41,217  
Attorney for Applicants

**Enclosures:**

Form PTO/SB/08  
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	8	Attorney Docket Number	ICC-130.0 (4564/85124)
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### Complete if Known

Application Number	10/082,014
Filing Date	February 21, 2002
First Named Inventor	Ashley J. Birkett
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	ICC-130.0 (4564/85124)

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number - Kind Code	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date If Appropriate
	A1	4,220,717	09/02/1980	Kuo	435	101	
	A2	4,356,170	10/26/1982	Jennings et al.	424	92	
	A3	4,539,205	09/03/1985	Goodman, et al.	514	45	
	A4	4,544,500	10/01/1985	Bittle et al.	260	112.5	
	A5	4,619,828	10/28/1986	Gordon	424	92	
	A6	4,643,992	02/17/1987	Goodman, et al.	514	45	
	A7	4,767,842	08/30/1988	Stevens	530	324	
	A8	4,818,527	04/04/1989	Thornton, et al.	424	88	
	A9	4,882,145	11/21/1989	Thornton, et al.	424	88	
	A10	4,882,317	11/21/1989	Marburg et al.	514	54	
	A11	4,886,663	12/12/1989	Houghten	424	88	
	A12	4,886,782	12/12/1989	Good et al.	514	12	
	A13	4,987,237	01/22/1991	Myers, et al.	549	222	
	A14	5,011,828	04/30/1991	Goodman, et al.	514	45	
	A15	5,023,179	06/11/1991	Lam, et al.	435	172.3	
	A16	5,057,540	10/15/1991	Kensil, et al.	514	25	
	A17	5,093,318	03/03/1992	Goodman, et al.	514	45	
	A18	5,110,732	05/05/1992	Benfey et al.	435	172.3	
	A19	5,126,258	06/30/1992	Lerner et al.	435	188.5	
	A20	5,143,726	09/01/1992	Thornton, et al.	424	88	
	A21	5,187,086	02/16/1993	Janda	435	146	
	A22	5,208,152	05/04/1993	Hilvert et al.	435	119	
	A23	5,236,825	08/17/1993	Iverson et al.	435	68.1	
	A24	5,248,611	09/28/1993	Benkovic et al.	435	280	
	A25	5,304,252	04/19/1994	Condra et al.	134	2	

Examiner Signature		Date Considered	
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Sheet 2 of 8

### Complete if Known

Application Number	10/082,014
Filing Date	February 21, 2002
First Named Inventor	Ashley J. Birkett
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	CC-130.0 (4564/85124)

A26	5,387,744	02/07/1995	Curtiss, III et al.	424	235.1	
A27	5,478,726	12/26/1995	Shinnick et al.	435	724	
A28	5,618,988	04/08/1997	Hauptmann, et al.	800	205	
A29	5,639,854	06/17/1997	Sia et al.	530	324	
A30	5,656,472	08/12/1997	Ausich et al.	435	193	
A31	5,679,880	10/21/1997	Curtiss, III et al.	800	205	
A32	5,709,879	01/20/1998	Barchfeld, et al.	424	450	
A33	5,795,580	08/18/1998	Jennings et al.	424	244.1	
A34	5,888,799	03/30/1999	Curtiss, III	435	252.3	
A35	5,990,085	11/23/1999	Ireland, et al.	514	12	
A36	6,024,961	02/15/2000	Curtiss, III et al.	424	200	
A37	6,086,901	07/11/2000	O'Hagan, et al.	424	283.1	
A38	6,231,864	05/15/2001	Birkett	424	189.1	

### FOREIGN PATENT DOCUMENTS

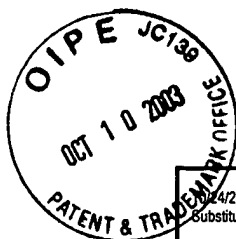
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>2</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	A39	EP 399 843 B1	11/28/1990	Chiron Corporation		
	A40	EP 421 635 B1	04/10/1991	The Wellcome Foundation Limited		
	A41	EP 671 948 B1	09/20/1995	SmithKline Beecham Biologicals S.A.		
	A42	EP 689 454 B1	01/03/1996	SmithKline Beecham Biologicals S.A.		
	A43	EP 786 521 A1	07/03/1997	UAB Research Foundation		
	A44	WO 91/13922	09/19/1991	Hoechst Celanese Corporation		
	A45	WO 95/17210	06/29/1995	SmithKline Beecham Biologicals S.A.		
	A46	WO 96/02555	02/01/1996	The University of Iowa Research Foundation		
	A47	WO 96/33739	10/13/1996	SmithKline Beecham Biologicals S.A.		
	A48	WO 97/18475	05/22/1997	Corixa Corporation		

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Substitute for form 1449A/PTO and 1449B/PTO**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 3 of 8 Attorney Docket Number ICC-130.0 (4564/85124)

**Complete if Known**

Application Number	10/082,014
Filing Date	February 21, 2002
First Named Inventor	Ashley J. Birkett
Art Unit	1645
Examiner Name	Not Yet Assigned
Attorney Docket Number	ICC-130.0 (4564/85124)

A49	WO 98/06851	02/19/1998	Board of Regents, The University of Texas System		
A50	WO 98/07320	02/26/1998	North Carolina State University		
A51	WO 99/07839	02/18/1999	Vlaams Interuniversitair Instituut Voor Biotechnologie		
A52	WO 99/40934	08/19/1999	Immune Complex Corporation		
A53	WO 99/52549	10/21/1999	SmithKline Beecham Biologicals S.A.		
A54	WO 00/32625	06/08/2000	Biogen, Inc.		
A55	WO 01/27281	4/19/2001	Medeva Europe Limited		
A56	WO 01/41759	06/14/2001	The Board of Trustees of the Leland Stanford Junior University		
A57	WO 01/98333	12/27/2001	Celltech Pharmaceuticals Limited		
A58	WO 02/13765	02/21/2002	Apovia, Inc.		
A59	WO 02/14478	02/21/2002	Apovia, Inc.		

**OTHER ART - NON PATENT LITERATURE DOCUMENTS**

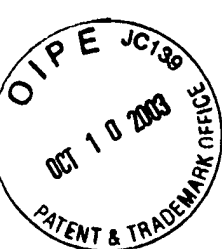
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A60	BASTIEN et al., "Protective Immune Responses Induced by the Immunization of Mice with a Recombinant Bacteriophage Displaying an Epitope of the Human Respiratory Syncytial Virus", <i>Virology</i> (1997) 234:118-122	
	A61	BENFEY et al., "Regulated Genes in Transgenic Plants", <i>Science</i> (April 1989) 244:174-181	
	A62	BIRKETT et al., "Development of a Vaccine to Prevent Falciparum Malaria Infection" - Poster presented by J. Haron at the Center for Advanced Technology and Medicine (CABM) Symposium, Rutgers University Medical Center on October 13-14, 1999	
	A63	BIRKETT et al., "A Modified Hepatitis B Virus Core Particle Containing Multiple Epitopes of the <i>Plasmodium falciparum</i> Circumsporozoite Protein Provides a Highly Immunogenic Malaria Vaccine in Preclinical Analyses in Rodent and Primate Hosts", <i>Infection and Immunity</i> (December 2002) 70(12):6860-6870	
	A64	BIRNBAUM et al., "Hepatitis B Virus Nucleocapsid Assembly: Primary Structure Requirements in the Core Protein", <i>J. Virol.</i> (1990) 64:3319-3330	
	A65	BOCKENSTEDT et al., "Identification of a <i>Borrelia burgdorferi</i> OspA T Cell Epitope That Promotes Anti-OspA IgG in Mice", <i>J. Immun.</i> (1996) 157:5496-5502	
	A66	BOTTCHER et al., "Determination of the fold of the core protein of hepatitis B virus by electron cryomicroscopy", <i>Nature</i> (1997) 386:88-91	

Examiner Signature	Date Considered
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Sheet	4	of	8	Attorney Docket Number	ICC-130.0 (4564/85124)
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### Complete if Known

Application Number	10/082,014
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First Named Inventor	Ashley J. Birkett
Art Unit	1645
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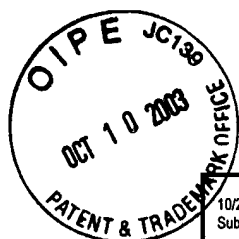
A67	BROWN et al., "Conservation of Determinants for Class II-Restricted T Cells Within Site E of Influenza Virus Hemagglutinin and Factors Influencing Their Expression", <i>J. Virol.</i> (May 1993) 67(5):2887-2893
A68	CALVO-CALLE et al., "Immunogenicity of Multiple Antigen Peptides Containing B and Non-Repeat T Cell Epitopes of the Circumsporozoite Protein of <i>Plasmodium falciparum</i> ", <i>J. Immunol.</i> (February 1993) 150(4):1403-1412
A69	CLARKE et al., "Expression and Immunological Analysis of Hepatitis-B Core Fusion Particles Carrying Internal Heterologous Sequences", <i>Vaccines</i> (1991) 91, Cold Spring Harbor Laboratory, New York, pp.313-318
A70	COLUCCI et al., "Identification of a Major Hepatitis B Core Antigen (HBcAg) Determinant by Using Synthetic Peptides and Monoclonal Antibodies", <i>J. of Immunology</i> (December 1988) 141:4376-4380
A71	CONWAY et al., "Visualization of a 4-helix bundle in the hepatitis B virus capsid by cryo-electron microscopy", <i>Nature</i> (1997) 386:91-94
A72	CORTHESEY et al., "A Pathogen-Specific Epitope Inserted into Recombinant Secretory Immunoglobulin A is Immunogenic by the Oral Route", <i>J. Biol. Chem.</i> (December 1996) 271(52):33670-33677
A73	CREGG et al., " <i>Pichia pastoris</i> as a Host System for Transformation", <i>Molecular and Cellular Biology</i> (December 1985) 5(12): 3376-3385
A74	CREGG et al., "High-Level Expression and Efficient Assembly of Hepatitis B Surface Antigen in the Methylophilic Yeast, <i>Pichia Pastoris</i> ", <i>Bio/Technology</i> (May 1987) 5:479-485
A75	DEIKMAN et al., "Interaction of a DNA Binding Factor with the 5'-Flanking Region of an Ethylene-Responsive Fruit Ripening Gene from Tomato", <i>EMBO J.</i> (1988) 7(11):3315-3320
A76	DEIKMAN et al., "Organization of Ripening and Ethylene Regulatory Regions in a Fruit-Specific Promoter from Tomato", <i>Plant Physiol.</i> (1992) 100:2013-2017
A77	DELPEYROUX et al., "A Poliovirus Neutralization Epitope Expressed on Hybrid Hepatitis B Surface Antigen Particles", <i>Science</i> (July 1986) 233:472-475
A78	DIRITA et al., "Deletion Analysis of the Mannopine Synthase Gene Promoter in Sunflower Crown Gall Tumors and <i>Agrobacterium tumefaciens</i> ", <i>Mol. Gen. Genet.</i> (1987) 207:233-241
A79	ENGELHARD et al., "The Insect Tracheal System: A Conduit for the Systemic Spread of <i>Autographa Californica</i> M Nuclear Polyhedrosis Virus", <i>Proc. Natl. Acad. Sci., USA</i> (April 1994) 91:3224-3227
A80	GALIBERT et al., "Nucleotide sequence of the hepatitis B virus genome (subtype ayw) cloned in <i>E. coli</i> ", <i>Nature</i> (October 1979) 281:646-650
A81	GALIBERT et al., "Nucleotide Sequence of a Cloned Woodchuck Hepatitis Virus Genome: Comparison with the Hepatitis B Virus Sequence", <i>J. Virol.</i> (January 1982) 41(1):51-65
A82	GALLINA et al., "A Recombinant Hepatitis B Core Antigen Polypeptide with the Protamine-Like Domain Deleted Self-Assembles into Capsid Particles but Fails to Bind Nucleic Acids", <i>J. Virol.</i> (1989) 63(11):4645-4652

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PTO/SB/08A & PTO/SB/08B (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

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First Named Inventor	Ashley J. Birkett
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A83	HELLING et al., "GM <sub>2</sub> -KLH Conjugate Vaccine: Increased Immunogenicity in Melanoma Patients after Administration with Immunological Adjuvant QS-21 <sup>1</sup> ", <i>Cancer Research</i> (July 1995) 55:2783-2788
A84	HILL et al., "Regions of <i>Yersinia pestis</i> V Antigen That Contribute to Protection Against Plague Identified by Passive and Active Immunization", <i>Infection and Immunity</i> (November 1997) 65(11):4476-4482
A85	INADA et al., "Synthesis of hepatitis B virus e antigen in <i>E. coli</i> ", <i>Virus Res.</i> (1989) 14:27-48
A86	"IUPAC-IUB Commission on Biochemical Nomenclature A One-Letter Notation for Amino Acid Sequences <sup>1-3</sup> Tentative Rules", <i>J. Biol. Chem.</i> (July 1968) 243(13):3557-3559
A87	KAHN et al., "The Surface Glycoproteins of <i>Trypanosoma cruzi</i> Encode a Superfamily of Variant T Cell Epitopes", <i>J. Immun.</i> (1997) 159:4444-4451
A88	KELLER et al., "Specific Expression of a Novel Cell Wall Hydroxyproline-Rich Glycoprotein Gene in Lateral root Initiation", <i>Genes &amp; Development</i> (1989) 3:1639-1646
A89	KELLY et al., "The Relationship Between Colonization and Haemagglutination Inhibiting and B Cell Epitopes of <i>Porphyromonas gingivalis</i> ", <i>Clin. Exp. Immunol.</i> (1997) 110:285-291
A90	KRATZ et al., "Native display of complete foreign protein domains on the surface of hepatitis B virus capsids", <i>Proc. Natl. Acad. Sci., USA</i> (1999) 96:1915-1920
A91	KRUGER et al., "Chimeric Virus-Like Particles as Vaccines", <i>Biol. Chem.</i> (March 1999) 380:275-276
A92	LAZDINA et al., "Priming of Cytotoxic T Cell Responses to Exogenous Hepatitis B Virus Core Antigen is B Cell Dependent", <i>J. of General Virol.</i> (2003) 84:139-146
A93	LINDSTROM et al., "Expression of Soybean Lectin Gene Deletions in Tobacco", <i>Developmental Genetics</i> (1990) 11:160-167
A94	LONDONO et al., "Immunisation of Mice Using <i>Salmonella typhimurium</i> Expressing Human Papillomavirus Type 16 E7 Epitopes Inserted into Hepatitis B Virus Core Antigen", <i>Vaccine</i> (1996) 14(6):545-552
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A96	LUCKOW, "Insect Cell Expression Technology" Chapter 7 in <i>Protein Engineering: Principle and Practice</i> , J.L. Cleland et al. eds., Wiley-Liss, Inc. (1996) pages 183-218
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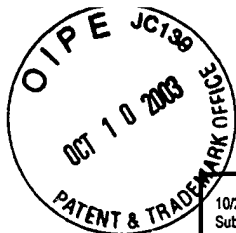
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Sheet	6	of	8	Attorney Docket Number	ICC-130.0 (4564/85124)
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**Completion if Known**

Application Number	10/082,014
Filing Date	February 21, 2002
First Named Inventor	Ashley J. Birkett
Art Unit	1645
Examiner Name	Not Yet Assigned

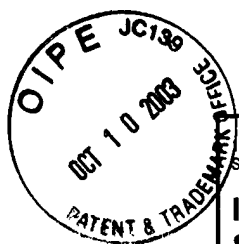
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		<b>Filing Date</b>	February 21, 2002
		<b>First Named Inventor</b>	Ashley J. Birkett
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<b>Sheet</b>	7 of 8	<b>Attorney Docket Number</b>	ICC-130.0 (4564/85124)

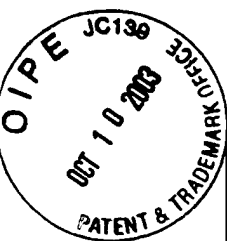
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